## PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Mary et al

Art Unit:

Examiner:

L. Maier

Application No.:

Not Yet Assigned

OF ENOXAPARIN

1623

Filed:

**Filed Concurrently Herewith** 

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Commissioner for Patents Washington, D.C. 20231

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Applicants submit herewith patents, publications, and other information of which they are aware, which they believe may be material, as defined in 37 C.F.R. 1.56(b), to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 C.F.R. 1.56(a). While the information referred to in this Information Disclosure Statement may be material pursuant to 37 C.F.R. 1.56(b), the filing of this Information Disclosure Statement is not intended to. pursuant to 37 C.F.R. 1.97(h), constitute an admission that any patent, publication or other information referred to is, or is considered to be, material to the patentability of this invention. Pursuant to 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information exists.

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The items listed with an asterisk on the attached PTO-1449 (modified) have been previously submitted by the applicant or cited by the Examiner in related applications of this series:

US Application No. 09/752,926

Therefore, a copy of the reference(s) are not enclosed with this Information Disclosure Statement.

Respectfully submitted,

Irving Newman, 22,638

Attorney for Applicant

Aventis Pharmaceuticals Inc. Patent Department Route #202-206 / P.O. Box 6800 Bridgewater, NJ 08807-0800 Telephone (908) 231-2785 Telefax (908) 231-2626 Aventis Docket No. ST00001US CNT

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STA	TEMENT E	BY A	APPLICANT	First Named Inventor	STUTZMANN		
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				U.S. PATENT DOCU	JMENTS	
Examiner Initials*	Cite No.1	U.S. Patent	Document  Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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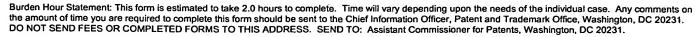
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		*AGG. TURPIE et al , THE LANCET; 1987; pp. 523-526					
		*BATH et al, Low Molecular Weight Heparin in Acute Stroke, EXPERT OPINION INVEST. DRUGS; Vol. 7; No. 8; 1998; pp. 1323-1330					
· · · · · · · · · · · · · · · · · · ·		*DAHL Trond et al, Dalteparin in Acute Ischemic Cerebrovascular Disease: A Safety Study, CEREBROVASCULAR DISEASES; Vol. 7; No. 1; 1997; pp. 23-33					
		*ELIAS et al, LA REVUE DE MEDECINE INTERNE; 1; Vol. XI; 1990; pp. 95-98					
		FAREED J et al, Biochemical and Pharmacologic Inequivalence of Low Molecular Weight Heparins, Ann. NY Acad. Sci., Vol. 556, 1989, pp 333-353					
		*GORDON David Lee et al., Low Molecular Weight Heparins and Heparinoids and Their Use in Acute or Progressing Ischemic Stroke, CLIN. NEUROPHARMACOL.; Vol. 13; No. 6; 1990; pp. 522-544					
		*HARDENBERG et al, Enoxaparin is Superior to Unfractionated Heparin in the Prevention of Thromboembolic Events in Medical Patients at Increased Thromboembolic Risk, BLOOD; Vol. 94; No. 10pt1.suppl.1; Abstract 1767; 1999; pp. 399a					
		*HILLBORN M et al, Comparison of the Efficacy of the Low Molecular Weight Heparin Enoxaparin with Ubfractionated Heparin in the Prevention of Deep einThrombosis in Patients with a Cute Ischemic Stroke, BLOOD; Vol. 94; No. 20. Supl, pt1; abstract no.798; Nov. 15,1999; pp. 183a					
		*JIANYOU et al, Low-MolWt. Heparin in Treatment of Acute Cerebral Infarction, CHEMICAL ABSTRACTS; Vol. 127; No. 24; Abstract No. 326219z; 1997; pp. 54					
		JONAS S et al, Is Low Molecular Weight Heparin a Neuroprotectant, Annal New York Academy of Sciences, Vol. 825, Oct. 1997, pp 389-393					

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Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
		*KAY et al, Low-Molecular-Weight Heparin for the Treatment of Acute Ischemic Stroke, NEW ENGLAND J. MED.; Vol. 333; No. 24; 1995; pp. 1588-1593	
		*KAY et al, Pilto Study of Low Molecular Weight Heparin in the Treatment of Acute Ischemic Stroke, STROKE; Vol. 25; No. 3; 1994-03; pp. 684-685	
		*LI Ping-An et al., Posttreatment with Low Molecular Weight Heparin Reduces Brain Edema and Infarct Volume inRats Subjected to Thrombotic Middle Cerebral Artery Occlusion, BRAIN RES.; Vol. 801; No. 1-2; 1998; pp. 220-223	
		*PRATT J et al., Enoxaparin reduces cerebral edema after photothrombotic injury in the rat, HAEMOSTASIS, 1998, Vol. 28, pages 78-85	
		*PRINS et al, Prophylaxis of Deep Venous Thrombosis with a Low Molecular Weight Heparin (Kabi 2165/Fagmin) in Stroke Patients, HAEMOSTASIS; Vol. 19, No. 5; 1989; pp. 245-250	
		*RYU et al, Heparin Reduces Neurological Impairment After Cerebral Air Embolism in the Rabbit, STROKE; Vol. 27; No. 2; 1996; pp. 303-310	
		*SAMANA M M et al., Acute Ischemic Stroke and Heparin Treatments, THROMB. HAEMOSTASIS; Vol. 78; No. 1; 1997; pp. 173-179	
		*STULLKEN ET AL, The Effects of Heparin on Recovery from Ischemic Brain Injuries in Cats, ANESTH. ANALOG; Vol. 55; No. 5; 1976; pp. 683-687	
	-	*TAIST INVESTIGATORS, Tinzaparin in Acute IschemicStroke Trial (TAIST), STROKE; Vol. 30; No. 1; 1999-01; pp. 163	
		*YANAKA et al , Reduction of Brian Injury Using Heparin to Inhibit Leukocyte Accumulation in a Rat Model of Transient Focal Cerebral Ischemia. II. Dose-Response Effect and the Therapeutic Window, J. NEUROSURG.; Vol. 85, No. 6; 1996; pp. 1108-1112	

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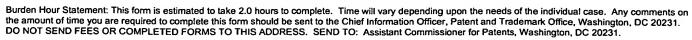
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		*ZHENG Jinzhi, Clinical Study on Low-MolWt. Heparin (LLMWH) for Treatment of Acute Cerebral Infarction, CHEMICAL ABSTRACTS; Vol. 130; No. 1; Abstract No. 366b; 1999; pp. 44			
		*, Physicians' Desk Reference, 49th Edition, pages 1968-1969, 1995			
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